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(54) **Medico-surgical collection bags.**

(57) An ostomy bag (4) has two vents one of which (54) is filtered and the other of which (64) is unfiltered. An adhesive strip (66) is used to seal the vents and can be peeled back to open them. In use, the vent is opened so that by pulling the walls (40 and 42) of the bag (4) apart, air is drawn through the vents into the bag. The vent is then closed to trap air in the bag and keep the front wall (42) away from the rear wall (40) in the region of the opening (48).

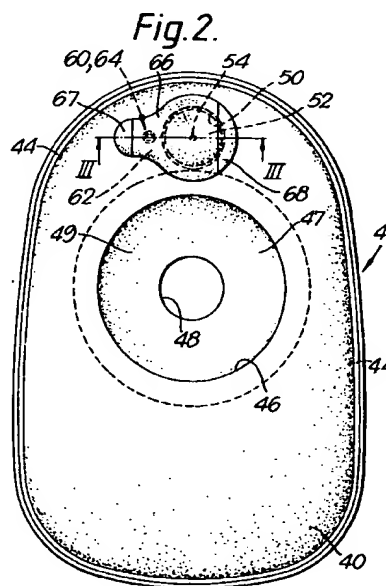
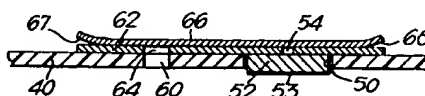


Fig. 3.



This invention relates to medico-surgical collection bags for body waste products of the kind comprising a front wall and a rear wall of flexible material, the rear wall having an opening into the bag by which waste material can enter the bag, means securing the bag to the wearer and a vent in one of the walls.

The invention is more particularly concerned with ostomy bags and their methods of use.

Ostomy bags are used to collect faecal matter from a surgically-made stoma where a part of the patient's bowel is brought to the skin of the abdomen. The bags are usually of flexible plastics material and are attached to the patient by means of an adhesive which may be on the bag itself around its opening, or on a separate patient fitment to which the bag can be coupled and uncoupled. It is common practice to provide the bag with a vent to allow for the escape of flatus gas; a filter, such as incorporating activated charcoal, may be included in the vent to reduce odour from vented gas.

One problem experienced with ostomy bags is referred to as "pancaking". This is where faecal matter, instead of dropping through the bag opening to the bottom of the bag, collects on the front wall of the bag opposite the opening. The collection of faecal material in this region obstructs the opening into the bag and can lead to escape of material between the seal of either the bag to the skin, or the bag to the patient fitment, or the patient fitment to the skin. It can also, in some cases, lead to detachment of the bag. The risk of pancaking is aggravated when the front wall lies close to the opening. Because the bags are supplied flat, it is usual for the front and rear walls to be in contact or close proximity when removed from their packaging. The action of attaching the bag to the wearer may, in some cases, involve pressing the front wall rearwardly towards the skin so as to bring the adhesive on the rear wall of the bag into contact with the skin or patient fitment. If the bag has a vent, it is possible, after attachment of the bag, for the front wall of the bag to be gripped and pulled forwardly away from the rear wall and the opening, the vent allowing air to enter the bag as this is done. Although this may reduce the risk of pancaking initially, it can be seen that, as air in the bag gradually escapes through the vent (such as caused by external pressure from clothing), the front wall can move rearwardly towards the opening and thereby increase the risk of pancaking. If the bag has no vent, it will not be possible to pull the front wall forwardly because of the vacuum this creates.

Another problem with vented bags relates to the mounting of the filter on the vent, because this must allow for efficient filtering whilst avoiding expensive assembly operations.

It is an object of the present invention in its various aspects to provide a medico-surgical collection bag that can be used to avoid these problems.

According to one aspect of the present invention there is provided a medico-surgical collection bag of the above-specified kind, characterised in that the vent is sealable such that when the vent is open, the front wall can be pulled away from the rear wall and such that when the vent is closed, gas is trapped within the bag.

The vent preferably includes a filter for reducing odour in gas exiting through the vent. The vent may include an aperture in the one wall, the filter being of disc shape with lateral dimensions smaller than the aperture, the gas-impermeable member being secured to the outer surface of the one wall around the aperture and to the outer surface of the filter such as to support it within the aperture, and the gas-impermeable member having an opening therethrough overlying the filter such that when the vent is open gas can escape from the bag through the filter and the opening. The inner surface of the filter may be gas impermeable so that gas flow is through the edge of the filter radially to the opening in the gas-impermeable member. The vent preferably has two vent passages one of which is filtered and the other of which is unfiltered. The vent may include a flexible adhesive strip by which the vent can be sealed. Two vent passages may open at locations spaced from one another such that either of the vent passages can be exposed by peeling back the flexible adhesive strip.

According to another aspect of the present invention there is provided a method of use of a medico-surgical collection bag of the kind comprising a front wall and a rear wall of flexible material, the rear wall having an opening into the bag by which waste material can enter the bag, means for securing the bag to the wearer, and a vent in one of the walls, characterised in that the method includes the steps of opening the vent, pulling the walls apart so that air enters the bag through the vent and subsequently sealing the vent to trap air within the bag and thereby keep the two walls separated from one another in the region of the opening.

A two-part ostomy bag assembly and its method of use, in accordance with the present invention, will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a sectional side elevation view of the assembly;

Figure 2 is a view of the rear side of the bag; and

Figure 3 is a transverse section to an enlarged scale along the line III - III of Figure 2.

The ostomy bag assembly is of the two-part kind, comprising a patient fitment 2 and a collection bag 4. The patient fitment 2 consists of a bendable plastics disc 20 with an adhesive rear surface 21 that is, in use, secured to the wearer's skin 6 around a stoma 8 which projects through a central aperture 24 in the fitment. A shallow collar 26 projects around the aperture 24 for use in locating with the bag 4.

The bag 4 comprises a rear wall 40 and a front wall 42 of a flexible plastics material, which may be w.c. disposable, sealed together around their outer edge 44. The front wall 42 is uninterrupted and impermeate, and is presented outwardly, away from the wearer's skin. The rear wall 40 has an opening 46 of diameter about 75mm and a flexible flange 47 with a diameter of about 95mm which has an adhesive rear surface that is stuck to the inside of the wall 40 around the opening 46. The flange 47 has a central aperture 48 of diameter about 25mm which provides the opening through which material discharged from the stoma 8 can enter the bag 4. That part of the rear surface of the flange 47 which is exposed within the aperture 46 in the wall 40 provides an annular adhesive region 49 by which the bag can be secured to the front surface of the patient fitment 2.

Located directly above the opening 46 there is a first circular vent aperture 50 in the rear wall 40 which is about 25mm in diameter. A circular disc filter 52 of activated carbon fabric, about 23mm in diameter is located within the first vent aperture 50. The inner face of the filter 52 has a layer 53 of a gas-impermeable material bonded to it whereas the outer face of the filter is adhered to a strip of transparent tape 62. The tape 62 covers the filter 52 and, where it overlaps the filter, adheres to the outer surface of the rear wall 40. The tape 62 has an opening 54 about 2mm in diameter located centrally of the filter 52. Because the layer 53 prevents gas flow through the inner face of the filter 52, flow is radially-inwardly through the edge of the filter and out through the opening 54 in the tape 62. In this way, a long gas path through the filter is produced with the most efficient filtering. Flow into the filter 52 at its edge is facilitated by the clearance between the edge of the filter and the aperture 50. Mounting the filter in this way can be accomplished readily by automated assembly operations whilst also giving effective filtering.

In alternative arrangements, the filter disc could be located internally or externally of the bag.

The bag 4 also has a second venting passage provided by an unfiltered vent aperture 60 which is located about 18mm to the left of the filtered vent aperture 50. The second vent aperture 60 is about 3mm in diameter and opens directly into the bag. The tape 62 also overlies the region around the aperture 60 and has an opening 64 in alignment with the vent aperture 60.

The region around the two apertures 50 and 60 is protected by the tape 62 adhered to the outer surface of the rear wall 40. The tape 62 is self-wound, single-sided, pressure-sensitive adhesive tape such as that sold by 3M under code 8415.

The bag 4 is completed by a vent sealing tape 66 which adheres to the rear face of tape 62 to extend over both the apertures 50 and 60 and thereby prevent flow of gas therethrough. The tape 66 is of the

same material and size as the tape 62 and is located in register with the underlying tape 62, with the adhesive surface of the sealing tape in contact with the non-adhesive surface of the underlying tape. At opposite ends of the sealing tape 66 there are two loose peel tabs 67 and 68 formed by paper slips adhered to the adhesive side of the tape. In this way, either tab 67 or 68 can be grasped and the tape 66 peeled off. This does not disturb the underlying tape 62 because the force required to remove the sealing tape 66 in the peel mode is less than that required to remove the underlying tape in the shear mode.

Although it might be possible to seal the vents 50 and 60 by the sealing tape 66 alone, without the underlying tape 62, it has been found that the action of unpeeling the sealing tape can stretch the wall 40 of the bag and lead to wrinkling. This can make it difficult to reapply the sealing tape 66 in a way that provides an effective seal.

The assembly is used in the following way. The patient fitment 2 is adhered to the skin around the stoma in the usual way. The bag 4 is held up to the patient fitment 2, with both vent apertures 50 and 60 closed by the sealing tape 66, so that the adhesive region 48 around the bag opening 46 adheres to the front surface of the patient fitment. To produce an effective seal, the user may have to press the front wall 42 firmly against the adhesive region 49 so that this is pressed into contact with the patient fitment 2; this has the effect of expelling most of the residual air in the bag 4 around the join with the patient fitment 2 before the seal is completed.

Once the bag 4 is securely attached to the patient fitment 2, the user can, if he wishes, admit air to the bag in order to reduce the risk of pancaking. This is done by peeling the sealing tape 66 back so that the unfiltered vent aperture 60 is exposed. The user then grips the front wall 42 and pulls it forwardly away from the rear wall 40. This creates a reduced pressure within the bag 4 which sucks in air through the vent aperture 60. The user then smooths the sealing tape 66 back over the aperture 60 so that the air cannot escape from the bag. In this way, the trapped air keeps the front wall 42 away from the rear wall 40, so that the risk of faeces collecting on the rear wall where they enter the bag is considerably reduced.

If gas should build up in the bag 4, this can be released by the user peeling back the sealing tape 66 to expose either the filtered opening 54 or the unfiltered opening 60, as desired. The gas is allowed to escape until the bag 4 reaches its desired inflation level and the sealing tape 66 is replaced.

If the user does not find pancaking to be a problem, he can permanently expose the filtered vent by peeling back the sealing tape 66 and folding a part of the adhesive surface onto itself so that the tape remains adhered to the bag, sealing the unfiltered vent.

It will be appreciated that the invention in its va-

rious aspects could be used with other two-part assemblies, such as that described in EP 476847, but is not confined to two-part bag assemblies and could be used with bags that are adhered directly to the user's skin.

#### Claims

1. A medico-surgical collection bag for body waste products comprising a front wall and a rear wall of flexible material, the rear wall having an opening into the bag by which waste material can enter the bag, means for securing the bag to the wearer, and a vent in one of the walls, characterised in that the vent (60, 64, 50, 52, 54, 66) is sealable such that when the vent is open, the front wall (42) can be pulled away from the rear wall (40) and such that when the vent is closed, gas is trapped within the bag (4). 10 15 20
2. A medico-surgical collection bag according to Claim 1, characterised in that the vent includes a filter (52) for reducing odour in gas exiting through the vent (50). 25
3. A medico-surgical collection bag according to Claim 2, characterised in that the vent includes an aperture (50) in the one wall (40), that the filter (52) is of disc shape with lateral dimensions smaller than the aperture (50), that a gas-impermeable member (62) is secured to the outer surface of the one wall (40) around the aperture (50) and to the outer surface of the filter (52) such as to support it within the aperture, and that the gas-impermeable member (62) has an opening (54) therethrough overlying the filter (52) such that when the vent is open gas can escape from the bag (4) through the filter (52) and the opening (54). 30 35 40
4. A medico-surgical collection bag according to Claim 3, characterised in that the inner surface (53) of the filter (52) is gas impermeable so that gas flow is through the edge of the filter (52) radially to the opening (54) in the gas-impermeable member (62). 45
5. A medico-surgical collection bag according to any one of Claims 2 to 4, characterised in that the vent has two vent passages (50, 54 and 60, 64) one of which (50, 54) is filtered and the other of which (60, 64) is unfiltered. 50
6. A medico-surgical collection bag according to any one of the preceding claims, characterised in that the vent includes a flexible adhesive strip (66) by which the vent can be sealed. 55

7. A medico-surgical collection bag according to Claims 5 and 6, characterised in that the two vent passages (50, 54 and 60, 64) open at locations spaced from one another such that either of the vent passages can be exposed by peeling back the flexible adhesive strip (66). 5

8. A method of use of a medico-surgical collection bag of the kind comprising a front wall and a rear wall of flexible material, the rear wall having an opening into the bag by which waste material can enter the bag, means for securing the bag to the wearer, and a vent in one of the walls, characterised in that the method includes the steps of opening the vent (60, 64, 50, 52, 54, 66), pulling the walls (40, 42) apart so that air enters the bag (4) through the vent (60, 64) and subsequently sealing the vent to trap air within the bag and thereby keep the two walls separated from one another in the region of the opening (48). 10 15 20

Fig. 1.

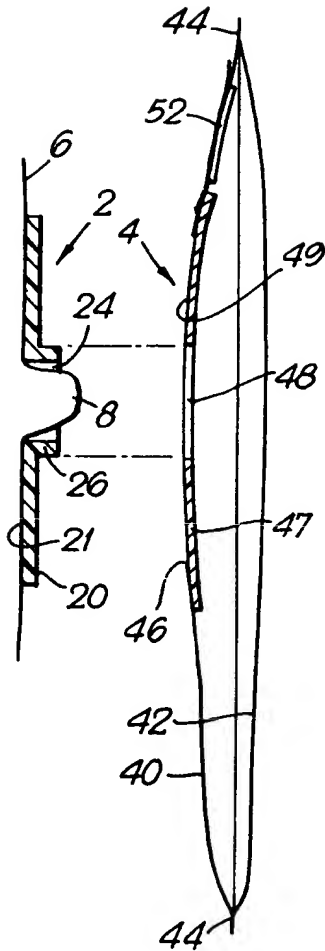


Fig. 2.

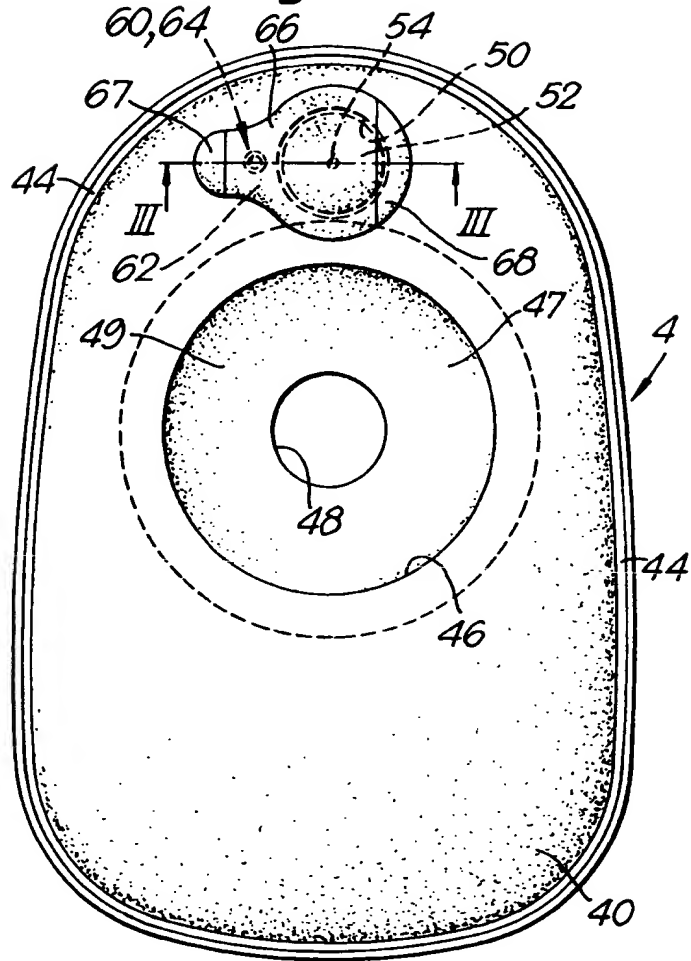
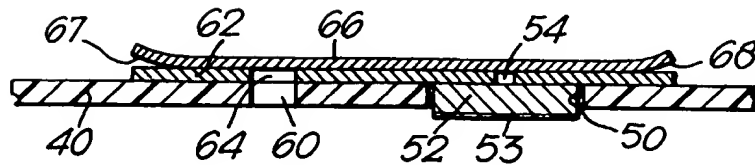


Fig. 3.





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# EUROPEAN SEARCH REPORT

Application Number

EP 92 30 7778

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. CL.5)
X	EP-A-0 142 262 (SQUIBB) * page 4, line 19 - page 5, line 5; figures 1,2 *	1	A61F5/441 A61F5/445
Y	----	2,4,5,7	
X	US-A-4 938 750 (LEISE) * column 2, line 15 - line 50; figure 1 *	1,6	
Y	----	2,7	
X	EP-A-0 156 164 (BEIERSDORF) * page 1, line 14 - line 23 * * page 4, line 29 - page 5, line 3; figures 1,2 *	1,2	
Y	US-A-4 938 749 (JENSEN) * abstract; figure 1 *	5	
A	----	3	
Y	EP-A-0 089 110 (COLOPLAST) * abstract; figure 1 *	2,5	
A	----	3	TECHNICAL FIELDS SEARCHED (Int. CL.5)
Y	EP-A-0 130 019 (SQUIBB) * page 6, line 22 - line 27; figures 1,3 *	5	A61F
A	----	1,5	
A	BE-A-804 946 (HOLLISTER) * page 6, paragraph 2 - page 7, paragraph 1; figures 1-9 *	3	
Y	----	4,5	
A	GB-A-2 185 404 (SMITHS) * page 2, line 3 - line 11 *	3,4	
A	US-A-3 902 496 (EAKIN)	9	
The present search report has been drawn up for all claims			
Place of search <b>THE HAGUE</b>		Date of completion of the search <b>07 JANUARY 1993</b>	Examiner <b>PAPONE F.</b>
<p><b>CATEGORY OF CITED DOCUMENTS</b></p> <p>X : particularly relevant if taken alone  Y : particularly relevant if combined with another document of the same category  A : technological background  O : non-written disclosure  P : intermediate document</p> <p>T : theory or principle underlying the invention  E : earlier patent document, but published on, or after the filing date  D : document cited in the application  L : document cited for other reasons</p> <p>Δ : member of the same patent family, corresponding document</p>			

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